IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HERON THERAPEUTICS, INC., *Plaintiff*, v. FRESENIUS KABI USA, LLC, *Defendant*.	§ § § § § § § § § § §	**FILED UNDER SEAL** Civil Action No. 22-985-WCB

MEMORANDUM OPINION AND ORDER

This is a Hatch-Waxman Act patent case involving U.S. Patent Nos. 9,561,229 ("the '229 patent") and 9,974,794 ("the '794 patent"). Plaintiff Heron Therapeutics, Inc. is the owner of both patents. Heron moves for summary judgment on two discrete issues. Dkt. No. 109. Defendant, Fresenius Kabi USA, LLC moves under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), to exclude the opinions of two of Heron's expert witnesses. For the reasons set forth in this opinion, Heron's motion for summary judgment is GRANTED IN PART. Fresenius's *Daubert* motions are both GRANTED IN PART.

I. Background

The asserted patents are directed to "emulsion formulations and systems for intravenous or parenteral administration of aprepitant for treatment of emesis." '229 patent at col. 1, ll. 15–17.[1]

[1] The specifications of the asserted patents are substantially identical. For purposes of this order, all citations to the '229 patent's specification also apply to the '794 patent at the same line and page number.

Aprepitant is a pharmaceutical compound indicated for the treatment and prevention of nausea and vomiting associated with emetogenic cancer chemotherapy. At the time of the invention, aprepitant was administered orally. Because aprepitant is used to treat vomiting, however, oral administration is undesirable, as patients are likely to regurgitate the drug. For that reason, the inventors sought "to formulate aprepitant as a liquid suitable for parenteral or intravenous administration." '229 patent at col. 1, ll. 47–49.

The asserted patents contain both composition and method claims. Claims 1–11 of both the '794 and '229 patents (the "composition claims") are directed to an aprepitant emulsion. Claims 12–21 of both patents (the "method claims") are directed to a procedure for administering that aprepitant emulsion. For purposes of the present motion, claims 1 and 12 of the '794 patent are representative, except that claims 1 through 11 of the '794 patent recite a "physically stable pharmaceutical composition," while claims 1 through 11 of the '229 patent do not contain a "physically stable" limitation. Claims 1 and 12 of the '794 patent recite:

> 1. A physically stable pharmaceutical composition comprising:
> 0.4 wt/wt % to 1.0 wt/wt % aprepitant;
> 13 wt/wt % to 15 wt/wt % egg yolk lecithin;
> 9 wt/wt % to 10 wt/wt % soybean oil; and
> a pH modifier, wherein the pH modifier is sodium oleate;
> wherein the pH of the composition ranges from 7.5 to 9.0, wherein the ratio of egg yolk lecithin to aprepitant (wt %:wt %) ranges from about 18:1 to 22:1.
>
> 12. A method for treating nausea and vomiting in a subject in need thereof comprising administering to the subject the pharmaceutical composition according to claim 1.

'794 patent, at col. 22, ll. 57–65; *id.* at col. 24, ll. 1–3.

Heron submitted infringement contentions explaining how the product for which Fresenius seeks approval in its Abbreviated New Drug Application ("Fresenius's ANDA product") meets all the limitations of the asserted claims. Dkt. No. 110-1, Ex. M. Fresenius did not initially submit

non-infringement contentions as to the composition claims beyond arguing that invalid claims cannot be infringed. *See* Dkt. No. 110-1, Ex. C. at 14–16 (responding to interrogatory regarding non-infringement contentions). As to the method claims, Fresenius argued only that it did not "teach, instruct, or encourage the use of [the accused] product in 'treating' nausea and vomiting." *Id.* at 16. Fresenius raised a more detailed noninfringement argument for the first time in its responsive expert reports. *See* Dkt. No. 110-1, Ex. D at ¶ 17–18 (explaining that Heron's infringement contentions and Fresenius's ANDA reported the concentration of its ingredients on a weight per volume basis, whereas the patent claims recited the concentration of the ingredients on a weight per weight percentage basis).

II. Legal Standard

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's decision in *Daubert*. Under those authorities, the trial court is assigned the task of ensuring that an expert's testimony rests on a reliable foundation and is relevant to the task at hand. *Daubert*, 509 U.S. at 597. In particular, the court must determine whether the reasoning or methodology underlying the expert's testimony is scientifically valid and whether the reasoning or methodology can properly be applied to the facts of the particular case. *Id.* at 593. The *Daubert* framework applies broadly to "scientific, technical, or other specialized knowledge," and the rules of evidence require a trial judge to determine whether that testimony "has 'a reliable basis in the knowledge and experience of the relevant discipline.'" *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999) (quoting *Daubert*, 509 U.S. at 592).

The court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" if the evidence is such that a reasonable jury could return a

verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). For an issue on which the moving party bears the burden of proof at trial, as in this case, the party seeking summary judgment must "establish the absence of a genuine factual issue." *Resol. Tr. Corp. v. Gill*, 960 F.2d 336, 340 (3d Cir. 1992). If the motion does not persuasively establish that no factual issue exists, summary judgment should be denied "even if no opposing evidentiary matter is presented." *Id.* Once the moving party with the burden of proof makes a showing that there is no genuine factual issue, that party is entitled to summary judgment "unless the non-moving party comes forward with probative evidence that would demonstrate the existence of a triable issue of fact." *In re Bressman*, 327 F.3d 229, 238 (3d Cir. 2003); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 233–23 (1986); *Meyers v. Brooks Shoe Inc.*, 912 F.2d 1459, 1461 (Fed. Cir. 1990); *Anderson*, 477 U.S. at 250.

It is an act of infringement to submit an Abbreviated New Drug Application "for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A). To prove infringement under the Hatch-Waxman Act, a plaintiff must establish the traditional elements of direct, induced, and/or contributory infringement. *See H. Lundbeck A/S v. Lupin Ltd.*, 87 F.4th 1361, 1368 (Fed. Cir. 2023); *Allergan, Inc. v. Alcon Lab'ys, Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003) ("The only difference in the analysis of a traditional infringement claim and a claim of infringement under section 271(e)(2) is the timeframe under which the elements of infringement are considered."). However, "when a product is sold with an infringing label or an infringing instruction manual, such a label is evidence of an intent to induce infringement." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1334 (Fed. Cir. 2021).

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those

skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). "Indefiniteness, as a subset of claim construction, is a question of law." *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014); *see also IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1380 (Fed. Cir. 2005). To the extent that indefiniteness is based on underlying facts, "[a]ny fact critical to a holding on indefiniteness must be proven by the challenger by clear and convincing evidence." *Cox Commc'ns, Inc. v. Sprint Commc'n Co.*, 838 F.3d 1224, 1228 (Fed. Cir. 2016) (quoting *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003)).

III. Fresenius's Daubert Motions

Fresenius moves to exclude opinions and testimony from Drs. Steven Little and Jeffrey Hale. Fresenius seeks to exclude Dr. Hale's opinions in their entirety, arguing that he is unqualified to speak on the subjects at issue and that his opinions apply an incorrect legal test. Fresenius seeks to exclude Dr. Little's opinions regarding the long-felt need for the invention as merely parroting those of another expert. Fresenius also seeks to exclude Dr. Little's opinions on the doctrine of equivalents as conclusory.

1. Opinions of Dr. Hale

Dr. Hale's expert report, Dkt. No. 103-2, Ex. B, presents opinions on two subjects. First, he discusses general background information about neurokinin-1 receptor antagonists, which is the category of drugs to which aprepitant belongs. Second, he discusses attempts in the industry to develop alternative formulations of aprepitant, and in particular, intravenous formulations. In doing so, he challenges the opinions of Fresenius's expert, Dr. Barrett Rabinow, regarding what a person of ordinary skill in the art would know about formulating aprepitant. *Id.* at ¶ 36. Dr. Hale further explains what a pharmaceutical scientist would have understood about the pertinent art in 2014. *Id.* at ¶¶ 17, 28.

Fresenius objects to Dr. Hale's opinions on three grounds. First, Fresenius argues that Dr. Hale is not himself a person of ordinary skill in the art and therefore cannot provide reliable testimony on the relevant issues. Second, Fresenius argues that Dr. Hale applied an incorrect standard for a person of ordinary skill in the art that does not accord with either party's definition. Third, Fresenius argues that Dr. Hale incorrectly applied a "lead compound analysis," which applies to patents in which the claim covers an active ingredient rather than a formulation. Based on those objections, Fresenius seeks to have Dr. Hale's opinions excluded in their entirety.

Heron does not challenge Fresenius's assertion that Dr. Hale is not an ordinary artisan. Instead, Heron argues that there is no general requirement that an expert witness be a person of ordinary skill in the pertinent art. It is true that an expert need not be a person of ordinary skill for the expert's testimony to be admissible. However, "[t]o offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art." *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376–77 (Fed. Cir. 2022); *id.* at 1377 ("[T]o be qualified to offer expert testimony on issues from the vantage point of an ordinarily skilled artisan in a patent case, an expert must at a minimum possess ordinary skill in the art."); *see also Bial-Portela & CA. S.A. v. Alkem Lab'ys Ltd.*, No. 18-304, 2022 WL 4244989, at * 7 (D. Del. Sept. 15, 2022) (excluding the opinions of two experts, a medical doctor and a researcher with a Ph.D. in pharmaceutical sciences, in a case in which a person of ordinary skill in the art was defined as someone having both of those qualifications).

Most of Dr. Hale's opinions easily satisfy Rule 702 and *Daubert*. Three paragraphs, however, relate to the expectations of a person of ordinary skill in the art. Dkt. No. 103-2, Ex. B at ¶¶ 17, 28, and 36. Paragraphs 17 and 28 of Dr. Hale's report state what a pharmaceutical

scientist in 2014 would have anticipated or understood about aprepitant for purposes of considering an intravenous aprepitant formulation. For that reason, those particular portions of Dr. Hale's report exceed the scope of Dr. Hale's permissible testimony under *Kyocera*. 22 F.4th at 1376–77.

A different portion of Dr. Hale's report, paragraph 36 of the report, challenges the validity of Dr. Rabinow's opinion regarding the expectations of an ordinary artisan, but it does so purely based on his personal knowledge of the history of the development of aprepitant. As such, that paragraph does not involve testimony "from the vantage point of an ordinarily skilled artisan in a patent case." *Id.* at 1377. Accordingly, only paragraphs 17 and 28 of Dr. Hale's report will be excluded. Those paragraphs are the only paragraphs in which Dr. Hale equates a "pharmaceutical scientist in 2014" to a person of ordinary skill in the art, so their exclusion moots Fresenius's challenge regarding Dr. Hale's definition of a person of ordinary skill.

Fresenius's final argument is not really a challenge to Dr. Hale's opinions, but instead is a challenge to Heron's legal position that a lead compound analysis is appropriate in this case. However, no determination has been made regarding the legal sufficiency of Heron's validity theory in this case. Fresenius's challenge therefore provides no basis to exclude the opinions of Dr. Hale, who is qualified to testify on matters falling within his expertise, including the portions of his report other than paragraphs 17 and 28.

For the foregoing reasons, paragraphs 17 and 28 of Dr. Hale's expert report are excluded. The remainder of his opinions are admissible.

2. Opinions of Dr. Little

Fresenius moves to exclude two categories of opinions expressed by Dr. Little: his infringement opinions based on the doctrine of equivalents and his validity opinions relating to the long-felt unmet need for the invention.

1. Infringement Opinions

Dr. Little first alluded to the doctrine of equivalents in his opening report, Dkt. No. 106-3, Ex. C at ¶ 301, in which he reserved the right to "address equivalency of any claim term for which Fresenius disputes infringement." In his reply report, Dr. Little set forth a doctrine of equivalents opinion on three subjects: the scope of the wt/wt% limitations, induced infringement of the method claims, and the physical stability characteristics of Fresenius's ANDA product. Dkt. No. 106-5, Ex. E at ¶¶ 52–57. Fresenius argues that all three opinions should be excluded under *Daubert*, 509 U.S. 579, and *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1977).[2]

Dr. Little's opinions regarding the scope of the wt/wt% limitations will be excluded, but not for the reasons Fresenius argues. Instead, the opinions disclosed in paragraph 54 of Dr. Little's reply report, Dkt. No. 106-5, Ex. E, will be excluded because they are superseded by the court's claim construction, *see infra* section IV(A)(2), which largely tracks Dr. Little's doctrine of equivalents position on the same subject.

Dr. Little's opinion regarding the equivalence of the method claims rebuts an argument made by Dr. Rabinow. *See* Dkt. No. 106-5, Ex. E at ¶ 55 (citing the paragraph of Dr. Rabinow's opinion to which the doctrine of equivalents opinion responds). Dr. Little's opinion, however, merely challenges the premise of Dr. Rabinow's position on the merits. *Id.* Dr. Little does not argue that a specific aspect of Fresenius's product or its administration method is equivalent to the claims of the asserted patents. In other words, Dr. Little's report does not disclose a doctrine of equivalents theory despite his purported invocation of the doctrine. For that reason, I will not

[2] *Pennypack* addresses late disclosure of information by one party. Here, the portions of Dr. Little's opinions at issue rebut the opinions of Dr. Rabinow. For that reason, there is no issue of late disclosure.

exclude the substance of Dr. Little's opinion on this subject, but Dr. Little will not be permitted to testify that the method claims infringe under the doctrine of equivalents.

Dr. Little's opinion regarding the physical stability limitations has the same character as his opinion regarding the method claims. In his reply expert report, Dr. Little states that any differences between Fresenius's product and that of the claims "would be insubstantial" with respect to the physical stability limitations because there would be no differences at all." *Id.* at ¶ 57. His opinion is not that Fresenius's ANDA product's features are equivalent to those of the claims (a doctrine of equivalents argument). Instead, his opinion is that the testing Heron conducted is equivalent to the testing the court described as proving that a formulation is physically stable. As with the prior issue, Dr. Little's opinion will not be excluded, but he will not be permitted to testify that Fresenius's ANDA product meets the physical stability limitations under the doctrine of equivalents.

2. Invalidity Opinions

Dr. Little's invalidity opinions discuss, among other things, the long-felt unmet need for an intravenous aprepitant formulation. *See* Dkt. No. 106-6, Ex. F at ¶¶ 310–13. Dr. Little is a chemical engineer, not a medical doctor. As such, he lacks the clinical experience to speak directly to the long-felt need issue, so on that issue he adopted the opinion of a medical doctor retained by Heron. Fresenius objects to Dr. Little's incorporation of that opinion as merely parroting the views of another expert. *See* Dkt. No. 104 at 3 (citing *Loeffel Steel Prod., Inc. v. Delta Brands, Inc.*, 387 F. Supp. 2d 794, 808 (N.D. Ill. 2005), amended, No. 01 C 9389, 2005 WL 8178971 (N.D. Ill. Sept. 8, 2005) and *Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty.")).

But Dr. Little has not become the mouthpiece for another expert. "It is well settled that one expert may rely upon another expert's opinion in formulating his own." *Shire Viropharma Inc. v. CSL Behring LLC*, No. CV 17-414, 2021 WL 1227097, at *29 (D. Del. Mar. 31, 2021) (quoting *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 286 F.R.D. 266, 271 (W.D. Pa. 2012)); Fed. R. Evid. 703. Fresenius's own lead cases acknowledge as much. *See Loeffel*, 387 F. Supp. 2d at 808; *Dura Auto. Sys*, 285 F.3d 613 ("[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert."). That is all that Dr. Little has done here. Although Dr. Little may not testify to his personal expertise regarding clinical matters, he may incorporate the opinions of other qualified experts in his analysis of secondary considerations of obviousness.

IV. Heron's Motion for Summary Judgment

Heron moves for summary judgment on two issues. First, it moves for summary judgment that Fresenius's ANDA product infringes all claims of the '229 and '794 patents. Second, Heron moves for summary judgment that the "physically stable" limitation that appears in the claims of the '794 patent is not indefinite.

A. Infringement

Most of Heron's assertions regarding infringement are unrebutted. Fresenius raises four specific issues on which it argues that Heron's motion for summary judgment should be denied. First, Fresenius argues that Heron's expert's opinions go beyond the scope of Heron's infringement contentions and therefore should not be credited. Second, Fresenius argues that there are lingering factual disputes as to whether Fresenius's ANDA product satisfies the weight percentage limitations of the asserted claims. Third, Fresenius argues that Heron's testing does not demonstrate that Fresenius's ANDA product satisfies the physical stability limitations of the

'794 claims. Fourth, Fresenius argues that there is a genuine factual dispute as to whether Fresenius has the requisite knowledge and specific intent to induce infringement of the asserted claims.

1. Expert Opinions

In his opening expert report Dr. Little stated that converting from a mass per volume percentage to the claimed weight per weight percentage is trivial. Fresenius argues that because Heron failed to disclose that position in its infringement contentions, Heron should not be permitted to elicit testimony to that effect at trial. Fresenius further argues that, without Dr. Little's opinion regarding the conversion from mass per volume to weight per weight percentages (wt/wt%), Heron cannot prove infringement.

"Infringement contentions must serve the purpose of providing notice to Defendants of Plaintiff's infringement theories beyond that which is provided by the mere language of the patent." *Wi-Lan Inc. v. Vizio, Inc.*, No. 15-CV-788, 2018 WL 669730, at *1 (D. Del. Jan. 26, 2018). Heron's infringement contentions assert that Fresenius's ANDA product meets each of the wt/wt% claim limitations. Heron's contentions also identify the weights per volume of each component in Fresenius's ANDA product. *See generally* Dkt. No. 110-1, Ex. M. Heron's contentions therefore put Fresenius clearly on notice of its infringement theory that the weight per volume figures reported for Fresenius's ANDA product satisfy the wt/wt% limitations of the claims. Heron was not obligated to add that it would be trivial for a person of ordinary skill in the art to convert from one to the other, a point that Fresenius's own expert conceded in his deposition. *See* Dkt. No. 110-2, Ex. S at 290:24–291:8, 291:20–24.

Because Heron's infringement contentions met its disclosure obligations regarding the concentrations of components in the accused product, Fresenius's procedural argument fails.

2. Weight Percentage Limitations

The parties' dispute as to the weight percentage limitation raises a claim construction issue on which the parties disagree. For that reason, I will construe that limitation in this order. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). Fresenius argues that the claims require specific wt/wt% amounts of various components. For example, Fresenius argues that the claimed 0.7 wt/wt% aprepitant means "exactly 0.7 wt/wt%." Dkt. No. 138 at 11. If Fresenius's argument were valid, Fresenius's ANDA product, which Heron alleges contains 0.72 wt/wt% aprepitant, would not infringe. The same is true regarding egg lecithin (14.4% in Fresenius's product, 14% claimed) and sucrose (5.4% in Fresenius's product, 5% claimed). Heron responds that the claims cover the range of values that round to the specified wt/wt%. For example, under Heron's construction, the 0.72 wt/wt% of aprepitant in Fresenius's product rounds to 0.7%, which means that the weight percentage in the accused product satisfies the weight percentage limitation of the claim. I agree with Heron's construction.

It would make no sense to limit the claims to exactly the wt/wt% set forth in the claims. It is physically impossible for a real-world composition to have *precisely* a prescribed wt/wt% of a particular component, so under Fresenius's construction the scope of the claims would always define a null set.

The standard practice in such cases is to read claims reciting a specific number as claiming the range of values that rounds to the claimed number, applying the standard scientific convention regarding significant figures. *See, e.g., Viskase Corp. v. American Nat'l Can Co.*, 261 F.3d 1316, 1320 (Fed. Cir. 2001); *Noven Pharms., Inc. v. Actavis Lab'ys UT, Inc.*, No. CV 15-249, 2016 WL 3625541, at *3 (D. Del. July 5, 2016); *see also Valeant Pharms. Int'l Inc. v. Mylan Pharms. Inc.*, 955 F.3d 25, 34 (Fed. Cir. 2020) (applying significant figures convention to a claimed range); *U.S.*

Philips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1377–78 (Fed. Cir. 2007) (same); *Arbutus Biopharma Corp. v. Moderna, Inc.*, No. CV 22-252, 2024 WL 1434526, at *8 (D. Del. Apr. 3, 2024) (same). Applying the standard significant figures convention to the wt/wt% limitations at issue in this case yields Heron's proposed construction.

In some cases, the intrinsic record provides reasons to deviate from the standard rounding convention. *See, e.g., AstraZeneca AB v. Mylan Pharms. Inc.*, 19 F.4th 1325, 1330 (Fed. Cir. 2021) (reversing district court's construction, which applied the standard significant figures rounding convention to the claimed percentage; crediting the specification's disparagement of deviation within the rounding range and construing the term to apply to a narrower range). But Fresenius has identified nothing in the intrinsic record of this case that would suggest to a person of ordinary skill in the art that a different rounding convention should be used in construing the asserted claims. There is therefore no reason to deviate from the standard significant figures practice in this case.

For the reasons outlined above, the court construes 0.7 wt/wt% aprepitant to mean "greater than or equal to 0.65 and less than 0.75 percent aprepitant," 14% egg lecithin to mean "greater than or equal to 13.5 and less than 14.5 percent egg lecithin," and 5% sucrose to mean "greater than or equal to 4.5 and less than 5.5 percent sucrose." It is not necessary to construe all wt/wt% limitations in the claims at this point because Fresenius has not challenged them, but the same analysis would apply to those limitations absent a compelling reason to deviate from it. Fresenius

therefore has not identified any specific limitations that would not be met under Heron's construction that applies standard rounding principles.[3]

3. Physical Stability Limitations

I have construed the physical stability limitations to mean, in part, that no aprepitant crystals are present after at least seven days based on 4x-10x optical microscopy testing. *See* Dkt. No. 54 at 14–15. Heron did not conduct the specific test called for in the claims. In concluding that this limitation was met, Dr. Little interpreted Fresenius's own testing on physical stability as showing that the claim limitation would be satisfied. *See* Dkt. No. 110-1, Ex. J at ¶¶ 82–84. Dr. Little further explained that Fresenius's testing "would provide at least an equivalent or greater method of detection as optical microscopy using 4x-10x objective lenses." *Id.*, Ex. L at ¶ 48, n.7. Fresenius argues that a factual question remains as to the sufficiency of Heron's evidence on this issue.

A party can prove that a limitation is met without following the precise testing protocol called for in the patent and the court's claim construction. *See Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, 477 F. Supp. 3d 306, 343 (D. Del. 2020) ("[T]here is no requirement that [the patentee demonstrate infringement] in the precise manner an accused infringer demands."). But while such evidence may be sufficient to satisfy Heron's burden on this issue, a reasonable factfinder could conclude that it is insufficient in this case. Accordingly, Heron has not met its burden of proving that no material issue of fact exists as to whether the physical stability limitation

[3] The 0.72 wt/wt% aprepitant in Fresenius's ANDA product, addressed above, was identified in Heron's reply brief. Dkt. No. 148 at 4. Egg lecithin and sucrose are identified in Dr. Little's expert report. Dkt. No. 106-4, Ex. E at ¶ 54. This order addresses those specific issues, however, because it is clear from Fresenius's brief that Heron accurately represented Fresenius's position on the issues.

is met. The fact that Fresenius's own expert concedes that he has "no reason to believe that Fresenius's ANDA product would not be physically stable after one week," Dkt. No. 110-2, Ex. S at 298:8–11 (cleaned up), does not matter if Heron has not met its initial burden. *See Resolution Trust*, 960 F.2d at 340.

In sum, it would be premature to decide this issue at the summary judgment stage and deny Fresenius an opportunity to discredit Heron's evidence. For that reason, summary judgment will be denied as to infringement of the claims of the '794 patent, all of which include the "physically stable" limitation.

4. Induced Infringement

Fresenius next argues that it does not induce infringement of the method claims of the two asserted patents, because there is a genuine issue of material fact as to whether Fresenius has the requisite knowledge and specific intent to induce infringement of those claims. It is undisputed that Fresenius's ANDA product instructs healthcare providers and patients to use Fresenius's ANDA product according to the claimed methods set forth in the product's label. Dkt. No. 110-1, Ex. J at ¶¶ 146–99, 261–97. Fresenius argues that summary judgment should not be granted on this issue because (1) Fresenius lacked the requisite knowledge and specific intent to induce infringement, (2) Fresenius believed the patents to be invalid, and (3) Fresenius's ANDA product is diluted before it is administered.

Fresenius's latter two arguments are misplaced and easily disposed of. Belief that a patent is invalid is not a defense to a claim of induced infringement. *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 642 (2015) ("The question the Court confronts today concerns whether a defendant's belief regarding patent validity is a defense to a claim of induced infringement. It is not."). And regardless of whether physicians may in some instances dilute Fresenius's ANDA

product before administering it, Fresenius's label instructs physicians to "not dilute" the formulation when administering it intravenously. *See* Dkt. No. 110-1, Ex. L at ¶ 32. The act of inducing physicians to use the drug in that manner, which Fresenius's label clearly does, is sufficient to support Heron's claim that Fresenius has the specific intent to induce infringement of the method claims.

Fresenius's argument regarding the knowledge requirement, however, is more persuasive. The knowledge prong has two related components: knowledge of the patent and knowledge of the induced acts of the third party. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (en banc).[4] Although Fresenius clearly had knowledge of the patent, given that this is a Hatch-Waxman case in which the suit was triggered by Fresenius's challenge to the patents, Heron has not shown the absence of a material fact regarding Fresenius's knowledge of the induced infringing acts. For that reason, summary judgment is inappropriate as to this issue.

Heron's motion for summary judgment that Fresenius infringed the method claims of both patents is therefore denied.

B. Indefiniteness

Indefiniteness as to the "physically stable" limitation has already been decided in this case. *See* Dkt. No. 54 at 5–12 (Markman order). Fresenius now argues that a new issue has surfaced regarding indefiniteness that is distinct from the issues the court already addressed. Fresenius's expert, Dr. Barrett Rabinow, maintains that the term "physically stable," as construed, "is

[4] Induced infringement also requires specific intent that the third party infringe the patent. *DSU Medical*, 471 F.3d at 1305 ("The mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." (quoting *Warner–Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed.Cir.2003)).

unbounded in the upper end of the time frame," making it indefinite. Dkt. No. 110-1, Ex. G at ¶ 308. He writes that a person of ordinary skill in the art "could choose to test at any time, and the subjectivity of the test time frame would dictate the result as to infringement or non-infringement." *Id.* Fresenius itself argues that this "upper boundary" defect is a different issue from the one decided in the *Markman* order, and that "as construed, there is no upper boundary for claims that are stable for 'at least one week,' rendering the term indefinite." Dkt. No. 138 at 18–19 (citing *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1253 (Fed. Cir. 2008)).

Fresenius's position is meritless. The claims at issue cover a composition that is stable for *at least* one week. If the composition is stable for longer than one week, it is still covered by the claim. No upper boundary is required for purposes of definiteness. This point was laid out clearly in *Exxon Research & Engineering Co. v. United States*, 265 F.3d 1371 (Fed. Cir. 2001), which addressed a claim to particles of average diameter greater than 5 microns. The court in that case explained:

> The claims do not contain any limitation on maximum particle size, and no limitation is required as a matter of definiteness. Thus, the claims expressly reach any composition with catalyst particles having an average diameter greater than five microns, no matter how large the particles may be; as such, there is no indefiniteness as to the scope of that limitation.

Id. at 1382. The sole case Fresenius cites in support of its indefiniteness position, *Halliburton Energy*, cites *Exxon* for the same proposition. 514 F.3d at 1253 n.5. ("[A] claim may contain a limitation that includes no explicit upper bound at all," which would not "present definiteness concerns").

Fresenius's position is contrary both to the court's rulings in this case and to established Federal Circuit caselaw. Heron's motion for summary judgment of no indefiniteness with respect to the "physically stable" limitation of the claims of the '794 patent is therefore granted.

IV. Conclusion

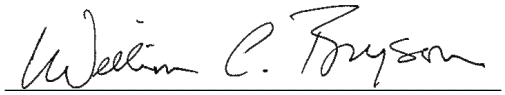
The rulings in this opinion are summarized as follows:

1. Fresenius's motion to exclude certain opinions of Dr. Hale is GRANTED IN PART. Paragraphs 17 and 28 of his opening report are excluded.
2. Fresenius's motion to exclude the opinions of Dr. Little is GRANTED IN PART. Paragraph 54 of his reply report is excluded, and Dr. Little may not testify that the physical stability limitations or method claims are met under the doctrine of equivalents.
3. Heron's motion for summary judgment of claims 1–11 of the '229 patent is GRANTED.
4. Heron's motion for summary judgment of claims 1–11 of the '794 patent is DENIED.
5. Heron's motion for summary judgment of claims 12–21 of the both the '229 and '794 patents is DENIED.
6. Heron's motion for summary judgment of no indefiniteness is GRANTED.

The briefs in this case were submitted under seal. For that reason, I have filed this opinion under seal. Within three business days of the issuance of this order, the parties are directed to advise the court by letter whether they wish any portions of this order to remain under seal, and if so which portions. Any request that portions of the order remain under seal must be supported by a particularized showing of need to limit public access to those portions of the order.

IT IS SO ORDERED.

SIGNED this 15th day of May, 2024.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE